

REMARKS

In the Office Action dated March 15, 2004, Claims 1-5 and 8-15 are pending and under consideration. Claims 1-5 and 8-15 are rejected under 35 U.S.C. §112, first paragraph, for allegedly lacking enablement. Claim 11 is rejected under 35 U.S.C. §112, second paragraph, as allegedly indefinite.

This Response addresses each of the Examiner's rejections. Applicants therefore respectfully submit that the present application is in condition for allowance. Favorable consideration of all pending claims is therefore respectfully requested.

Claims 1-5 and 8-15 are rejected under 35 U.S.C. §112, first paragraph, for allegedly lacking enablement. It is observed that the claims are directed to methods of stimulating growth and differentiation of mammalian pancreatic cells into three-dimensional cystic-ductular structures containing insulin-secreting cells.

The Examiner contends that the specification is only enabling for methods of stimulating growth and differentiation of mammalian pancreatic cells isolated from fetal pancreata, as described in Example 4 of the specification. The Examiner is of the opinion that the specification does not provide enablement for a method wherein the pancreatic cell is any precursor cell as defined in the specification.

Specifically, the Examiner indicates that the specification provides a broad definition of "pancreatic cell", which encompasses any precursor cell. The Examiner contends that it was highly unpredictable, at the time when the present application was filed, to practice the claimed method by employing precursor cells other than those residing in a pancreas, as indicated in *Stem Cells: Scientific Progress and Future Research Directions*, Department of Health and Human Services (June 2001). Thus, those skilled in the art would not have expected that the claimed

method could be readily practiced by employing stem cells obtained from brain, bone marrow, peripheral blood, dental pulp, spinal cord, blood vessels, skeletal muscle, epithelia of the skin and digestive system, cornea, retina and liver.

Furthermore, the Examiner states that as to embryonic stem cells, which are also "pancreatic cells" in view of the definition in the specification, neither the specification nor the art provides any guidance for establishing three-dimensional cystic-ductular structures containing insulin-secreting cells developed from ES cells.

Applicants respectfully submit that based on the description in the specification on page 12, those skilled in the art would understand the term "pancreatic cell" to encompass precursor cells that are committed to the pancreatic lineage.

With respect to the Examiner's allegation on the unpredictability of precursor cells other than those residing in a pancreas, Applicants respectfully submit that based on the present teaching, those skilled in the art would be able to practice the claimed methods by employing precursor cells other than those residing in a pancreas. However, in an effort to favorably advance prosecution of the present application, Applicants have amended the claims to specify the pancreatic cells as "isolated from fetal or adult pancreas". Applicants have also amended claims 5 and 12 to recite "pancreatic epithelial cells", instead of "pancreatic cells", to be consistent with claim 1. Applicants reserve the right to pursue the methods involving precursor cells other than those isolated from fetal or adult pancreas in a continuation application.

Applicants respectfully submit that those skilled in the art would be able to practice the methods as presently claimed, without undue experimentation. Therefore, the rejection under 35 U.S.C. §112, first paragraph, is overcome. Withdrawal of the rejection is therefore respectfully requested.

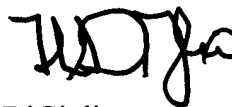
Claim 11 is rejected under 35 U.S.C. §112, second paragraph, as allegedly indefinite for reciting "pancreatic lineage embryonic stem cells".

The Examiner is of the opinion that an embryonic stem cell, by definition, cannot be committed to a particular lineage because an ES cell is pluripotent. The Examiner states that the Applicant seems to be referring to a pancreatic progenitor cell, which is recognized in the art to arise from embryonic stem cells. However, the Examiner indicates that a progenitor cell is also defined in the specification as an ES cell committed to a pancreatic cell lineage. Therefore, the Examiner contends that a recitation of "progenitor cell" would also be indefinite in view of the definition in the specification.

Applicants respectfully submit that claim 11 has been amended to recite "embryonic stem cells-derived precursor cells that are committed to the pancreatic lineage." Support for the amendment is found in the specification, e.g., on page 12, lines 23-28. Claim 11 as amended is not indefinite. Withdrawal of the rejection under 35 U.S.C. §112, second paragraph, is therefore respectfully requested.

In view of the foregoing amendments and remarks, it is respectfully submitted that the present application is in condition for allowance which action is earnestly solicited.

Respectfully submitted,



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